

STATE OF MICHIGAN
DEPARTMENT OF LABOR & ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE SERVICES

Before the Commissioner of Financial and Insurance Services

In the matter of

XXXXX

Petitioner

File No. 87135-001

v

**Physicians Health Plan of Mid-Michigan
Respondent**

**Issued and entered
This 15th day of February 2008
by Ken Ross
Acting Commissioner**

ORDER

**I
PROCEDURAL BACKGROUND**

On January 10, 2006, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Services under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* On January 17, 2008, after a preliminary review of the material submitted, the Commissioner accepted the request.

This case required a recommendation from a medical professional so the Commissioner assigned the matter to an independent review organization (IRO) which completed its review and sent its recommendation to the Commissioner on January 28, 2006.

**II
FACTUAL BACKGROUND**

The Petitioner is a member of Physicians Health Plan of Mid-Michigan (PHP), a health maintenance organization (HMO). Her drug benefits are defined in the prescription drug rider to her certificate of coverage.

When she was 27 years old she had a hysterectomy that brought on early menopause. The controversy over hormone replacement therapy caused her to discontinue the use of synthetic hormones and she then began using bio-identical hormone replacement therapy.

The Petitioner requested coverage from PHP for Biest, a compounded estrogen hormone replacement, and Armour Thyroid, a natural replacement for thyroid hormone. The request was denied.

The Petitioner exhausted PHP's internal grievance procedures and received its final adverse determination letter dated November 14, 2007.

III ISSUE

Did PHP properly deny the Petitioner coverage for Biest and Armour?

IV ANALYSIS

Petitioner's Argument

The Petitioner took Premarin for over 18 years but says it produced numerous side effects: dry skin, chronic constipation, hot flashes, night sweats, vaginal dryness, foggy thinking, memory lapses, depression, headaches, water retention, sleep disturbances, irritable bowel syndrome, weight gain, ovarian cysts, sugar cravings, decreased libido, cold body temperature, and thinning and itchy skin. But with the bio-identical hormones she says she only has to deal with constipation.

The Petitioner also says that the bio-identical hormones do not have the side effects of the formulary drugs. She contends that Biest has been highly effective for her, is not unproven or experimental, and should be covered.

XXXXX, DO, her physician, also supports her use of Biest. In a letter dated March 17, 2006, he stated in part:

In view of the findings of the Women's Health Initiative Study, it is no longer safe to recommend estrone to a patient. Recent

medical literature has shown that estadiol is required to maintain bone structure, and estriol is needed to prevent breast cancer. Consequently I have prescribed for her Biest as her estrogen therapy.

At PHP's grievance hearing, the Petitioner said she would pay for the Armour Thyroid herself if PHP would cover the Biest cream. However, PHP maintained its denial of coverage for both medications.

The Petitioner says using Biest has given her "a level of wellness I have not had since my hysterectomy in 1984." She also says the Armour Thyroid allows her more energy and fewer symptoms than Synthroid. She argues that PHP should cover these medications because they are medically necessary.

PHP's Argument

In its final adverse determination, PHP denied coverage for Biest and Armour Thyroid:

Physicians Health Plan of Mid-Michigan's...grievance committee reviewed your grievance for coverage of the medications Armour Thyroid and Biest cream. The original decision to deny your request was upheld because Armour Thyroid is not listed on Tier 1 or Tier 2 of the Prescription Drug List and there are formulary alternatives that are covered for your condition. The Biest cream is considered unproven and is specifically excluded from coverage.

Regarding the coverage for Biest, PHP based its denial on this exclusion in "Section 2: What's Not Covered – Exclusions" of the outpatient prescription drug rider:

5. Experimental, Investigational or Unproven Services and medications; medications used for experimental indications and/or dosage regimens determined by us to be experimental, investigational or unproven. This does not include any off-label usage of a Prescription drug product....

PHP argues that Biest is not covered because it is unproven.

PHP further says that Armour Thyroid is not covered because there are formulary alternatives available to treat the Petitioner's hypothyroidism. Under state law, PHP must cover drugs not included in its formulary when they are shown to be a medically necessary and

appropriate alternative to drugs on the formulary. See MCL 500.3406o. PHP reviewed the Petitioner's medical records and concluded there are formulary drugs available to treat her condition, and there was no information to establish the medical necessity of Armour Thyroid as an alternative to formulary drugs approved for her conditions.

Commissioner's Review

The questions of whether Biest is unproven and whether PHP must cover Armour Thyroid as a medically necessary non-formulary drug were submitted to an IRO. The IRO physician who reviewed this case is board certified in internal medicine and is in active practice.

The IRO report concluded that Biest was experimental or unproven:

The [IRO] Reviewer cited "FDA News" article released January 9, 2008, which states "bio-identical hormone replacement" (BHRT) products are unsupported by medical evidence and are not FDA approved. *New England Journal of Medicine* (NEJM) vol 356:1176-1178, March 15, 2007 "Menopausal Symptoms" states, "Bio-identical hormone replacement is not evidence-based therapy...compounded hormone preparations are not produced according to Federal Good Manufacturing Practice, and they are not approved by the FDA for safety and efficacy...."

The Reviewer recognized that the [Petitioner] reports success in alleviation of her symptoms with Biest cream, but as stated previously, there are other FDA approved and peer-recognized medications to treat menopausal symptoms. In the opinion of the Reviewer, Biest cream is experimental due to lack of FDA approval, the comment in NEJM, and lack of recognition by formularies. In addition, there are no large randomized clinical trials establishing safety or efficacy of Biest.

The IRO report further said that "the standard treatment for menopausal women is with conjugated equine estrogens such as Premarin or with estradiol, either in pill form or as a patch or as vaginal creams or gel."

The IRO report then went on to say:

Also, in the opinion of the Reviewer, Armour Thyroid is not medically necessary for [the Petitioner] since there are formulary alternatives available, i.e., Leoxyl or Synthroid available. Finally,

there are no benefits of Armour Thyroid over Leoxyl or Synthroid. The Health Plan's denial of coverage of this medication is reasonable.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded great deference by the Commissioner; it is based on extensive expertise and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case.

The Commissioner accepts the conclusion of the IRO expert that Biest is unproven and that Armour Thyroid has not been shown to be medically necessary for the Petitioner's hypothyroidism, and finds that PHP properly denied coverage for both medications under the terms of the Petitioner's prescription drug coverage.

V ORDER

The Commissioner upholds PHP's November 14, 2007, final adverse determination denying coverage for the Biest and Armour Thyroid.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the Circuit Court for the county where the covered person resides or in the Circuit Court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Services, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.